ANDA 070737/S-028

CHANGES BEING EFFECTED
APPROVAL

Ho pira Inc
275 North Field Drive
Bldg. H1-3S
Lake Fore t, IL 60045
Attention: Maria Hinklin
Director, Pfizer Global Regulatory Science

Dear Maria Hinklin:

Thi letter i in reference to your upplemental abbreviated new drug application (ANDA) received for review on May 20, 2022, ubmitted pur uant to ection 505(j) of the Federal Food, Drug, and Co metic Act (FD&C Act) for Verapamil Hydrochloride Injection USP, 5 mg/2 mL (2.5 mg/mL) and 10 mg/4 mL (2.5 mg/mL); (Single-do e Vial).

The sANDA, submitted as “Changes Being Effected," provides for revi ed Pre cribing Information to include drug interaction information regarding the co-admini tration of Verapamil and Ivabradine.

We have completed the review of thi ANDA and it i **approved**.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United State Pharmacopeia or official National Formulary (USP-NF) generally mu t comply with the compendial tandard for trength, quality, and purity, unle the difference in trength, quality, or purity i plainly tated on it label (ee FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot hare application- pecific information contained in ubmitted regulatory filing with third partie , which include USP-NF. To help en ure that a drug continue to comply with compendial tandard , application holder may work directly with USP-NF to revi e official USP monograph . More information on the USP-NF is available on USP’s web ite a http ://www.u pnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable tatute , regulation , and guidance , your ANDA may be ubject to certain requirement and recommendation po t approval, including requirement regarding change to approved ANDA , po tmarketing reporting, promotional material , and annual facility fee , among other . For information on po t-approval requirement s

and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https: www.fda.gov drugs abbreviated new drug application anda requirements and resources approved andas.

n

incerely yours,

{See appended electronic signature page}

For Rachel Goehe, Ph.D.
Director
Division of Labeling Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research n

Juliette U
La e i a i f

Digita l signed b Juliette La e i a i f
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